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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/690,353	10/16/2000	Douglas A. Collins	COP1003	2345

7590 03/01/2004

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Supplemental Notice of Allowability	Application No.	Applicant(s)	
	09/690,353	COLLINS ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *2/24/04*.

2. ☒ The allowed claim(s) is/are *1-3,5-19,28-32,37-46 and 56-63*.

3. ☐ The drawings filed on _____ are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *2/23/04* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

D. L. Jones 2/26/04
D. L. Jones
Primary Examiner
Art Unit: 1616

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Madeline Johnston on 2/23/04.

The application has been amended as follows:

Please replace the specification with the attached substitute specification.

After inserting the substitute specification, replace the first paragraph of page 1 of that specification with the following paragraph.

"Related Applications

This application is a CIP of PCT/US0010098 filed April 15, 2000 which claims priority to U.S. Provisional Application Serial No. 60/159,753 filed October 15, 1999."

Please replace all prior claim listings in the application with the following listing of claims.

(see attachment '**REPLACEMENT CLAIM SET**')

COMMENTS/NOTES REGARDING THE EXAMINER'S AMENDMENT ABOVE

2. The Examiner was given authorization to make changes appearing in the attached replacement claim set. Specifically, authorization was given to amend the original claims to be consistent with the 'replacement claim set' that was submitted in the amendment filed December 3, 2002. Also, in the Examiner's replacement claim set, authorizaiton was given to replace the second '45' appearing in claims 56, 57, 60, and 63 with '46' (there was a typographical error in the amendment filed December 3, 2002). In addition, the Examiner was asked and given authorization to update the continuing data in the specification. The first paragraph of the specification should read 'Related Applications: This application is a CIP of PCT/US0010098 filed April 15, 2000 which claims priority to U.S. Provisional Application Serial No. 60/159,753 filed October 15, 1999.' Finally, the Examiner was given authorization to handwrite text in the specification. Duplicate (readable) copies of the specification were submitted with Applicant's response filed December 3, 2002, but were inadventently not scanned during the imaging process.

ALLOWABLE CLAIMS

3. Claims 1-3, 5-19, 28-32, 37-46, and 56-63 are allowable over the prior art of record for reasons of record in the office action mailed 4/8/03.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

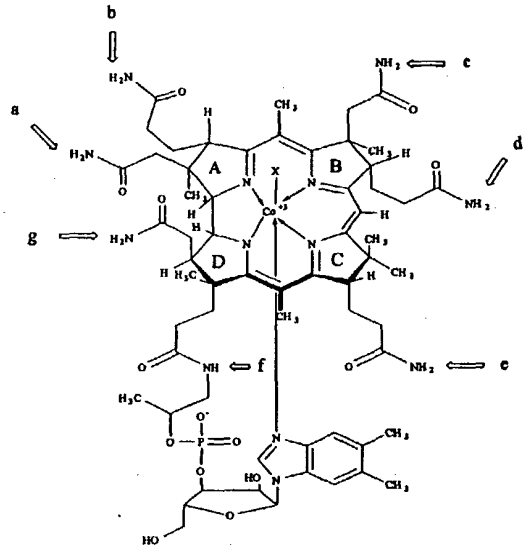
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1616

February 24, 2004

REPLACEMENT CLAIM SET

1) A compound wherein a residue of a compound of formula I



(I)

is linked to one or more peptide residues or amino acid residues wherein X is CN, OH, CH_3 or adenosyl, and at least one of the peptide residues or the amino acid residues is linked to one or more chelating groups comprising one or more metallic radionuclides; or a pharmaceutically acceptable salt thereof.

2) The compound of claim 1 wherein at least one of the one or more metallic radionuclides is a diagnostic radionuclide.

3) The compound of claim 1 wherein at least one of the one or more metallic radionuclides is a therapeutic radionuclide.

4) CANCELLED

5) The compound of claim 1 wherein the residue of a compound of formula I is linked to a peptide residue at the position of the b-carboxamide, d-carboxamide, e-carboxamide, or the 6-position of the compound of formula I.

6) The compound of claim 1 wherein the residue of a compound of formula I is linked to a peptide residue at the position of the b-carboxamide of the compound of formula I.

7) The compound of claim 1 wherein the residue of a compound of formula I is linked to a peptide residue at the d-carboxamide of the compound of formula I.

8) The compound of claim 1 wherein the residue of a compound of formula I is linked to a

18) The compound of claim 17 wherein the chelating group is DTPA.

19) The compound of claim 1 wherein the residue of a compound of formula I is linked to two peptide residues wherein at least one peptide residue is linked to one or more chelating groups comprising one or more metallic radionuclides.

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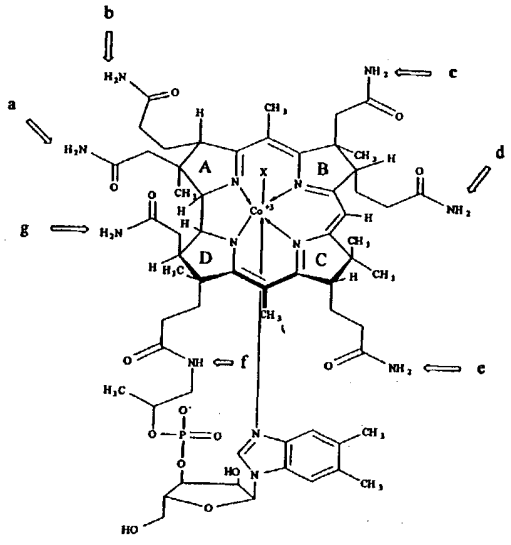
28) A compound wherein a residue of a compound of formula I



(I)

is linked to one or more residues of the formula -[NHCH[$(CH_2)_4NH_2$-DET]CO-]$_n$-Q wherein Q is H, (C_1-C_{14})alkyl, or a suitable carboxy protecting group; X is CN, OH, CH_3 or adenosyl; DET is a chelating group residue comprising a metallic radionuclide; and n is between 2 and about 20; or a pharmaceutically acceptable salt thereof.

29) The compound of claim 28 wherein the chelating group is DTPA.

30) The compound of claim 28 wherein each metallic radionuclide is independently Antimony-124, Antimony-125, Arsenic-74, Barium-103, Barium-140, Beryllium-7, Bismuth-206, Bismuth-207, Cadmium-109, Cadmium-115m, Calcium-45, Cerium-139, Cerium-141, Cerium-144, Cesium-137, Chromium-51, Cobalt-56, Cobalt-57, Cobalt-58, Cobalt-60, Cobalt-64, Copper-67, Erbium-169, Europium-152, Gallium-64, Gadolinium-153, Gadolinium-157 Gold-195, Gold-199, Hafnium-175, Hafnium-175-181, Holmium-166, Indium-111, Iridium-192, Iron-55, Iron-59, Krypton-85, Lead-210, Manganese-54, Mercury-197, Mercury-203, Molybdenum-99, Neodymium-147, Neptunium-237, Nickel-63, Niobium-95, Osmium-185 + 191, Palladium-103, Platinum-195m, Praseodymium-143, Promethium-147, Protactinium-233, Radium-226, Rhenium-186, Rhenium-188, Rubidium-86, Ruthenium-103, Ruthenium-106, Scandium-44, Scandium-46, Selenium-75, Silver-110m, Silver-111, Sodium-22, Strontium-85, Strontium-89, Strontium-90, Sulfur-35, Tantalum-182, Technetium-99m, Tellurium-125, Tellurium-132, Thallium-204, Thorium-228, Thorium-232, Thallium-170, Tin-113, Tin-114, Tin-117m, Titanium-44, Tungsten-185, Vanadium-48, Vanadium-49, Ytterbium-169, Yttrium-86, Yttrium-88, Yttrium-90, Yttrium-91, Zinc-65, or Zirconium-95.

31) The compound of claim 28 wherein n is about 8 to about 11.

32) The compound of claim 28 wherein the residue of a compound of formula I is linked to two residues of the formula P-[NHCH[$(CH_2)_4NH_2$-DET]CO-]$_n$-Q wherein P is H, (C_1-C_{14})alkyl, or a suitable amino protecting group; Q is H, (C_1-C_{14})alkyl, or a suitable carboxy protecting group; and DET is independently a chelating group residue comprising a metallic radionuclide and wherein n is 2 to about 20.

33) CANCELLED

34) CANCELLED

35) CANCELLED

36) CANCELLED

37) The compound of claim 1 wherein the residue of a compound of formula I is further linked to one or more detectable radionuclides.

38) The compound of claim 37 wherein the detectable radionuclide is a non-metallic radionuclide.

39) The compound of claim 38 wherein the non-metallic radionuclide is Carbon-11, Fluorine-18, Bromine-76, Iodine-123, or Iodine-124.

40) The compound of claim 37 wherein the detectable radionuclide is directly linked to the compound of formula I.

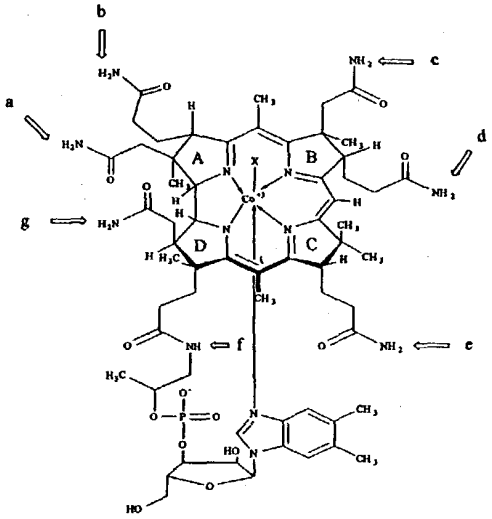
41) The compound of claim 37 wherein the detectable radionuclide is linked by a linker to the compound of formula I.

42) The compound of claim 41 wherein the linker is of the formula W-A wherein A is (C_1-C_6)alkyl, (C_2-C_6)alkenyl, (C_2-C_6)alkynyl, (C_3-C_8)cyclo-alkyl, or (C_6-C_{10})aryl, wherein W is -N(R)C(=O)-, -C(=O)N(R)-, -OC(=O)-, -C(=O)O-, -O-, -S-, -S(O)-, -S($O)_2$-, -N(R)-, -C(=O)-, or a direct bond; wherein each R is independently H or (C_1-C_6)alkyl; and wherein A is linked to one or more non-metallic radionuclides.

43) The compound of claim 41 wherein the linker is about 5 angstroms to about 50 angstroms, inclusive, in length.

44) The compound of claim 41 wherein the linker is linked to the 6-position of the compound of formula I or is linked to the residue of a-, b-, d- or e-carboxamide group of the compound of formula I.

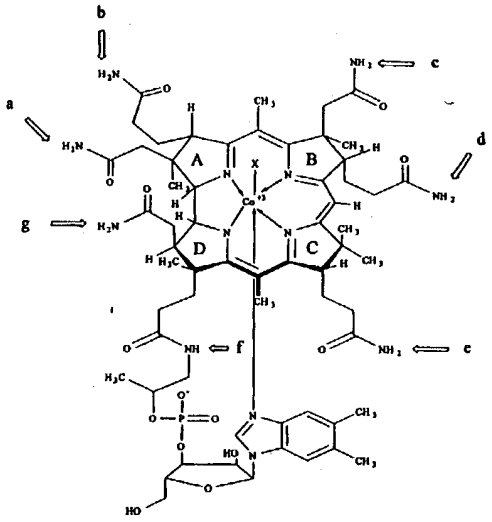
45) A compound wherein a residue of a compound of formula I



(I)

is linked to a residue of a peptide which is linked to one or more chelating groups comprising a metallic radionuclide; and X is CN, OH, CH_3 or adenosyl; or a pharmaceutically acceptable salt thereof.

46) A compound wherein a residue of a compound of formula I



(I)

is linked to a residue of an amino acid which is linked to one or more chelating groups comprising a metallic radionuclide; and X is CN, OH, CH_3 or adenosyl; or a pharmaceutically acceptable salt thereof.

47) CANCELLED

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56) A pharmaceutical composition comprising a compound of any one of claims 1, 2, 3, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 28, 29, 30, 31, 32, 37, 38, 39, 40, 41, 42, 43, 44, 45, or 46, and a pharmaceutically acceptable carrier.

57) A method for imaging a tumor in mammalian tissue comprising administering to the mammal an amount of a compound of any one of claims 1, 2, 3, 5, 6, 7, 8, 9, 10, 11, 12,

13, 14, 15, 16, 17, 18, 19, 28, 29, 30, 31, 32, 37, 38, 39, 40, 41, 42, 43, 44, 45, or 4 6 and detecting said compound.

58) The method of claim 57 wherein the mammal is a human.

59) The method of claim 57 wherein the mammalian tissue is located in the breast, lung, thyroid, lymph node, genitourinary system, musculoskeletal system, gastrointestinal tract, central or peripheral nervous system, head, neck, or heart.

60) A method for treating a tumor in a mammal comprising administering to the mammal an effective therapeutic amount of a compound of any one of claims 1, 2, 3, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 28, 29, 30, 31, 32, 37, 38, 39, 40, 41, 42, 43, 44, 45, or 46; wherein said compound comprises at lease one therapeutic radionuclide.

61) The method of claim 60 wherein the mammal is a human.

62) The method of claim 60 wherein the mammalian tissue is located in the breast, lung, thyroid, lymph node, genitourinary system, musculoskeletal system, gastrointestinal tract, central or peripheral nervous system, head, neck, or heart.

63) A compound of any one of claims 1, 2, 3, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 28, 29, 30, 31, 32, 37, 38, 39, 40, 41, 42, 43, 44, 45, or 4 6 for use in medical therapy or diagnosis.

64) CANCELLED

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69) CANCELLED